Dr. Brown testified that Plaintiff's test results were valid for lead and would not represent lead from background sources or from contamination. Dr. Brown opined that even though it may not be possible to establish a statistical significance between only two lead results, such results are independently significant and are adequate to show the actual presence of lead on the glassware. He specifically opined that Defendant's contamination or background theory was unsupported because the range of results, showing various lead levels for similar glasses, would not exist if the lead result was all from background.

Dr. Brown also identified the industry's own documents that acknowledge the presence of surface lead on glassware and discussed the differences to the painted surface that can result from different firing temperatures or times. (Brown Depo., 82:12-83:22, Trial Exs. 7 and 8.) Dr. Brown reviewed these documents and their discussion of the occurrence of "pitting" on some painted surfaces from firing – which pitting causes there to be a greater surface area for release of lead. (Brown Depo., 82:12-83:22, Trial Exs. 7 and 8.) Dr. Brown concluded that the occurrence of pitting could increase the surface area of paint available for the release of lead and effect the amount of lead leach that would occur between otherwise similar patterns. (Brown Depo., 82:12-83:22, Trial Exs. 7 and 8.)

Dr. Brown explained from a toxicological perspective the significant toxic effects to humans from any exposure to lead. Based upon his own studies and a thorough familiarity with the current medical and scientific research on the area, Dr. Brown explained how certain chemical groups exist in the blood that are critical to the formation of nerves in the developing human. (*See*, Brown Test. 8/7.) Lead is preferentially picked up by these chemicals and transported to the brain. In the brain, even extremely low levels of lead interfere with the development of the brain. He distinguished the harm to the brain by lead from that of Mercury. (*See*, Brown Test. 8/7.) Whereas Mercury can break the brain nerve proteins, lead destroys the entire cell body. (*See*, Brown Test. 8/7.) The effects of this destruction in a developing human are irreversible and irreparable. (*See*, Brown Test. 8/7.) Even at the lowest levels, lead is shown to accumulate in the

brain and cause decrements in fine motor control and IQ. (*See*, Brown Test. 8/7.) Though subtle, these effects are seen at lower and lower levels of lead exposure as the technology for detecting them advances. (*See*, Brown Test. 8/7.)

b. Dr. Callahan

Dr. Callahan is also a Ph.D. toxicologist who has extensive professional experience with industry (Chevron, Gradient Corp, Fluor Daniels, ABB Environmental), as well as working for the Massachusetts Dept. of Public Health. A significant portion of her educational foundation relates to neonatal lead exposure and neurochemistry. Specifically, she studied the neurochemical and other effects of lead through looking at lipid peroxidation and neuronal cellular damage and development. She teaches toxicology and risk assessment at Northeastern University and University of Massachusetts School of Public Health. (*See*, Callahan Test. 8/12.)

Like all of her toxicological assessments, Dr. Callahan approached her assessment of cosmetic exposure in this case by looking for the existence of lead in the product and the reasonable use patterns of the product to determine the different pathways of exposure. (*See*, Callahan Test. 8/12.) Dr. Callahan defined "lead", for purposes of Proposition 65, as including elemental lead and both inorganic and organic lead compounds. (Callahan Trial Test., 423-424). Dr. Callahan based this testimony on specific inquiries and conversations she had with unidentified employees of OEHHA. (Callahan Trial Test. 423-424). Dr. Callahan follows the EPA and Proposition 65 definition of exposure as all leaded cosmetics contacting the outer boundary of the human body. (Callahan Test., 10/27.) Specifically she investigated the concentrations of lead and exposure pathways for lipstick, eye shadow and eyeliner. She also looked at powder, foundation and blush. She reviewed photographs and actual samples of the products at issue and received test results showing underestimated lead concentration levels for each of the products. She further investigated reasonable consumer use and contacted resources at Tufts engineering and Proctor & Gamble to assist with the development of her foundation and opinions regarding the extent of consumer exposure from Defendants' leaded cosmetics. Other

than her conversations with Proctor & Gamble and her review of the ingredients, Dr. Callahan did not specifically know how lead was bound to the other materials in the cosmetic components. Dr. Callahan did testify that all of the molecules of lead in the matrix touch the skin and that the lead does not have to be released from the matrix in order to be absorbed through the skin.

Other than her discussion with Proctor & Gamble representatives, Dr. Callahan had no knowledge of how the lead was chemically combined with the other ingredients of the cosmetics. Dr. Callahan found consumer "exposure" to Defendants' cosmetics from the lead-containing cosmetics coming in contact with the boundary of the human body at the mouth, the eyes, the nose and the dermal areas surrounding these regions. Dr. Callahan also testified as to the significance of exposure to the cosmetics from their multiple re-applications and the extensive duration the cosmetics are in contact with the mouth, eyes and skin. Due to the friable nature of certain of the cosmetics, Dr. Callahan identified oral, ocular and ingestion exposure resulting from use of the components in the cosmetic kits and also opined that inhalation was a source of exposure to the lead-containing powders. (*See*, Callahan Test. 8/12.) For lipstick, she identified direct ingestion as well as indirect ingestion from hand-to-mouth, food-to-mouth, glass-to-mouth activity, etc. (*See*, Callahan Test. 8/12.) Dr. Callahan specifically opined that the amount of a substance ingested by an adult through hand-to-mouth activity is around 25%. She based this opinion on the 50% factor used by the CPSC for children and the fact that the EPA Exposure Factors Handbook says that adult ingestion on substances through hand-to-mouth activity is 50% less than that of children. (Callahan Trial Test., 187). For eye shadow and eyeliner, she identified dermal exposure and subsequent hand-to-mouth ingestion as well as direct entry through the nasolacrimal and other ducts around the eye, the hair follicles of the eyelash and the exposed, highly vascularized and non-lipid based membrane of the eyelids. (*See*, Callahan Test. 8/12.) Because the conjunctiva and mucosa of the eyelids and nasal passages don't have the lipid resistance to cosmetics that normal skin would, and because they are rich with blood vessels, the lead has a nearly

direct route to the bloodstream from these areas. (*See*, Callahan Test. 8/12.) Dr. Callahan relied on her prior experience with the area of ocular exposure from her consultation with the military on ocular absorption of chemical agents as well as her review and study of the literature describing significant lead poisoning from child and adult users of Kohl makeup in India (as published in Lancet medical journal). (*See*, Callahan Test. 8/12.) She also opined that hand-to-mouth activity from manual application or smoothing of the eye makeup resulted in ingestion exposure. (*See*, Callahan Test. 8/12.) Dr. Callahan also opined that inhalation exposure would occur during use of the powdered blush and other face makeup that aerosolize easily during application. (*See*, Callahan Test. 8/12.)

Based upon all of these resources, Dr. Callahan testified as to consumer exposure to lead from the reasonably foreseeable use of these products. She also testified that it would be possible to test humans for actual exposure to lead by looking for lead in the user's blood. Dr. Callahan acknowledged that the FDA had utilized analysis of blood lead levels to assess lead exposure levels from the use of certain hair dyes (that are required to be sold with a warning). She further opined, relying on her conversations with clerks at JC Penney and Macy's West, her experience as a woman and expertise in observing human behavior, that the cosmetics were marketed, packaged and used in such a way as to encourage (and result in) the simultaneous use of each type of cosmetic kit component with the other type. (Callahan Test., 46:12-19, 86:2-9). Dr. Callahan cautioned that there was no use of any cosmetic component of the kits, either singularly or together, from which no exposure would result.

Dr. Callahan testified that, in her opinion, during every single day in its development, the fetus, an organism one ten-thousandth of the size of an adult, is susceptible to immensely significant and similarly unreasonable risks from leaded blood circulating through its developing systems. Dr. Callahan was aware of no literature that demonstrated that a one-day exposure to lead actually caused any reproductive effect. The shortest exposure study that Dr. Callahan was aware of having been performed on lead exposure and adverse health effects was following 10 days of exposure to lead.

(Callahan Trial Test., 363:11-18.) However, Dr Callahan opined that the literature neither demonstrates nor excludes the possibility that lead causes adverse effects from one day of exposure. (Callahan Trial Test., 362:16-21.) She opined that during, at least, the first and last trimester of pregnancy the developing brain is sensitive to any neurotoxin and that "lead is surely a neurotoxin." (Callahan Trial Test., 362:28-363:10.)

Dr. Callahan discussed the biggest potential risk from the singular or combined group of cosmetics was that to the fetus. She provided testimony regarding the different stages of the development of the fetus and how, at each stage, the organism is extremely susceptible to minute levels of lead infiltration. She further testified to the fact that the damage lead can do, to the neurobehavioral mechanisms and systems of the developing fetus, is irreversible and irreparable. (*See*, Callahan Test. 8/12.)

Dr. Callahan also specifically discussed some of the most recent medical literature on the health effects of lead. Citing the Canfield article from the New England Journal of Medicine, she explained how it presented further scientific support of human developmental decrement from very low levels of exposure to lead. She explained that, in her opinion, a fetus or newborn has been demonstrated as losing up to 7.4 IQ points associated with blood lead levels within the first 10 micrograms per deciliter (µg/dL). (*See*, Callahan Test. 8/12.) Dr. Callahan stated there was literature supporting her opinion. (*See*, Callahan Test. 8/12.) Injuries caused by these low lead levels occur in the hippocampal region of the brain because lead is in the same valence state as calcium and passes the blood/brain barrier easily and include permanent losses to short-term memory and emotional development as well as the loss in IQ. (*See*, Callahan Test. 8/12.) These realized risks are caused by the increased susceptibility of the fetus during the process of organogenesis, particularly in the first three (3) months of pregnancy when the mother is perhaps being less careful about her physical status. (*See*, Callahan Test. 8/12.) Such exposures can also affect, amongst other things, male and female reproductive capacity. (*See*, Callahan Test. 8/12.) Dr. Callahan expressed the opinion that the exposures from using the components of cosmetic kits are continuing and accumulating throughout the

development of the fetus, or even the reproductive attempts of females using the cosmetics. (*See*, Callahan Test. 8/12.)

In addition to demonstrating consumer exposure to lead from foreseeable use of the Defendants' cosmetic kit components, Dr. Callahan testified that cosmetic kit usage resulted in exposures, even only on a daily basis, that exceed the Proposition 65 maximum allowable daily limit of .5 µg/day and also would exceed .5 µg/9 month gestation period for those that are pregnant. (Callahan Test. 10/27.) However, Dr. Callahan stated that she was not preparing a complete determination or analysis of the "level in question". Dr. Callahan acknowledged that she did not include exposure data for any exposure to the friable cosmetics that generated respirable powder during use. Dr. Callahan expressed the opinion that Plaintiff's lead concentration test result was incomplete and insufficient to be representative of actual lead concentration data for the cosmetics. She testified that the concentration data alone was insufficient for the purpose of calculating Defendant's "level of exposure" because (1) Plaintiff's digestion was incomplete and the concentration was significantly undervalued, (2) Defendant did not perform any testing to achieve the complete lead concentration data for any component, (3) not all of the products in a particular kit were tested and some other components could demonstrate a higher concentration and (4) no concentration data was provided for the respirable powders by either Plaintiff or Defendant. Nonetheless, Dr. Callahan not only testified that this concentration data was sufficient to establish a detectable exposure, but that even these significantly undervalued figures would demonstrated how easy it was to surpass even the .5 µg/day MADL of Proposition 65. As a contrast, however, Dr. Callahan also used the only produced complete digest data from the manufacturer's laboratory itself. Dr. Callahan expressed the opinion that the data provided by Kolmar demonstrated actual lead concentration results at least twice as much as the partial digest results from Plaintiff, but she did not know what methods were used to perform that test.[13] (Callahan Test.

[13] For example, plaintiff's highest concentration of lead from Fashion Fair's Beauty on The go II was 1.5 ug/gram (ppm) whereas Kolmar's own testing demonstrated a concentration of 4.5 ug lead/gram product. Similarly, where

10/27. Ex. 208.) Dr. Callahan further testified that one cannot do a calculation for statistical difference between Plaintiff's data and the Kolmar data because such a calculation is not appropriate with just two numbers. (Callahan Trial Test., 214:22-215:1.) Dr. Callahan opined, with respect to the Kolmar data that showed double the lead concentrations compared to Plaintiff's data, that "the manufacturer is being asked for the information, and I have no reason to think that he wouldn't be truthful with that." (Callahan Trial Test., 214:18-21.)

Moreover, Dr. Callahan testified that in her opinion the Proposition 65 "safe harbor" level of .5 micrograms of lead exposure per day is extremely outdated and subject to a strong movement in the scientific community for change. (Callahan Test. 10/27.) In fact, Dr. Callahan testified that in her opinion the .5 level, being based upon a blood-lead level that is no longer scientifically tenable or appropriate. (Callahan Test. 10/27.)

Dr. Callahan testified in her opinion as follows:

> The .5 level is based upon the 1978 OSHA PEL of 500 micrograms of lead exposure, via inhalation, per day. When promulgated, OSHA realized 500 micrograms per day would result in blood lead levels (BLLs) of approximately 40 micrograms(µg)/deciliter(dL). Moreover, OSHA recognized that even a BLL of 30 µg/dL was not safe, but would only "minimize" the risk of reproductive toxicity in both men and women. Thus, the 1978 LOEL was 30µg/dL BLL. The linear exposure equation thus determined that 375 µg lead inhaled per day would achieve the 30µg/dL BLL. Modern authority however, including the World Health Organization, Center for Disease Control, EPA, and the scientific community have recognized that the current lowest BLL at which adverse effects are observed is not the 1978 level of 30µg/dL, but 10µg/dL or even lower.

Dr. Callahan identified that the 10 µg/dL BLL comes from the American Society of Toxic Disease Registry (ASTDR) and that organization is currently in the process of reviewing the data for the purpose of revising it to a lower level. (Callahan Test. 10/27.) Nonetheless, even under the current observed effect level (LOEL) of 10 µg/dL, the

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plaintiff's highest Beauty On The go II lipstick lead concentration was .6 ug/gram, Kolmar's own testing demonstrated a concentration of 1.6 ug/gram.

inhalation exposure to appropriately achieve this level would be 125 µg lead per day (375µg/3). Converting to a NOEL results in 12.5 µg per day and adjusting to an MADL results in a permissible lead inhalation exposure limit of .0125 µg lead per day (125/10 = NOEL of 12.5, 12.5/1000 = MADL of .0125).

Even the modern relative MADL for ingestion is .0125 µg lead exposure per day. Dr. Callahan explained that the FDA recognizes that ingestion of 250 µg lead per day will approximately result in a BLL of 10µg/dL – which they also recognize is not without adverse health effects. Converting this exposure, from a LOEL into a NOEL, results in a NOEL level of 25 µg per day lead exposure. Converting this to a modern ingestion MADL results in a daily permissible ingestion exposure of lead, under Proposition 65, of .025 µg per day (25 NOEL/1000 = .025 MADL).

Dr. Callahan testified that for purposes of fetal protection, assessing exposures to pregnant women, the EPA requires analysis of exposures at the 95th percentile to ensure 95% of all fetuses are protected. Further, exposure analysis should only look at exposure to individuals of child bearing age since Proposition 65's warning requirement for lead relates to reproductive toxicity. Further, since the reproductive harm from lead exposure is presumed to occur on any day (thus every day) of fetal development, it is imperative to analyze the highest exposure to each individual during pregnancy. (Callahan Test. 10/27.)

To perform her Proposition 65 exposure analysis, Dr. Callahan included data on the concentration of lead in the lipstick multiplied by the reasonably anticipated rate of use of each product. To identify the appropriate rate, Dr. Callahan measured the area of the face and the duration of use as well as the number of additional contacts per day. To identify the area of the relevant facial portions, Dr. Callahan provided directions to others to measure both an anthropomorphic model's lips and eyes as well as a portrait artists 3-dimensional drawing of the same, relevant areas. The anthropomorphic model is known as KEMAR and is an anatomically average model of the human head. (Ex. 154.) There was no evidence that this KEMAR model had been used for the purpose of assessing the area covered by cosmetics used by women. The portrait artist used a human subject to

convert a 3 dimensional facial portrait of the eye and lips into a 2 dimensional graphic representation of their area. (Ex. 156.) The surface area of the cosmetic application areas of KEMAR was measured using triangulation and the portrait area was measured through an enlarged graph. The resulting eyeshadow areas measured 20 sq. cm. for the portrait and 16 sq. cm. for Kemar. Eyeliner area ranged from 25.5 cm length (portrait) to 12.75 cm long (Kemar – only one lid available to measure so represents 50% of actual). Lip area measured 6.5 sq. cm. from the portrait and 13.65 sq. cm. from KEMAR.

Dr. Callahan next calculated the weight of the applied cosmetic analysis by multiplying the area of cosmetic applied by its density. Using her two models as upper and lower bound exposure values, Dr. Callahan's calculations of the amount of cosmetic applied to a user's skin exceeded the .5µg/day level of § 12805. For the Macy's West Christian Dior Kit, the lower bound for exposure to the lipstick, eyeshadow and eyeliner was .87 µg/day with the upper bound at 8.88 µg/day. For the Macy's West Fashion Fair Beauty On The Go II (Plaintiff's data) the lower/upper bound concentrations were .42 µg/2.12µg per day for lipstick and eyeshadow only. Macy's West's Fashion Fair Glitter N Go the lower/upper bound concentrations were .85 µg/5.04 µg per day and also only for eyeshadow and lipstick only – not eyeliner or powder.

The lower/upper for J.C. Penney's Elizabeth Taylor Blockbuster was 1.73 µg/8.88 µg and their Haslton Holiday Evening Accessory Collection was 1.69 µg/8.99 µg lead per day (lipstick and eyeshadow only). The J.C. Penney Private Portfolio Professional Blockbuster was .90 µg/6.71 µg per day (for lipstick, eyeshadow and eyeliner). J.C. Penney's private label Luxurious Traincase lipstick alone delivered 1.72 µg lead/day where the IMS Cool Bag lipstick delivered .76 µg lead/day.

Dr. Callahan also identified the significant number of problems that existed with the data that defense expert Michael Lakin attempted to use for his "level of exposure" calculations. Dr. Callahan criticized the value of the CTFA data because it only included averages for actual lipstick use over 14 days and allowed no ability to identify how much a user was actually consuming on any single, relevant day. (Callahan Trial Test., 60:6-13,

179-180.) Dr. Callahan opined that this problem is critical in analyzing daily exposure potential under Proposition 65 because a woman in the study could use very little lipstick on one day and then a much larger amount the next day. (Callahan Trial Test., 61:13-21.) Indeed, Dr. Callahan testified that, by the very nature of an average, some of the numbers are going to be higher than the average. (Callahan Trial Test., 430:23-25.) Dr. Callahan's own use data, collected using standard EPA and California EPA techniques, was higher than Dr. Lakin's because she was looking at the actual single-day exposures at the 95% level and not the average exposures at some lesser level. (Callahan Trial Test., 183, 347). She testified that the use rates she identified for her analysis were specifically not those rates of exposure that a woman would experience every day, but only a woman's exposure on a typical day of actual high use. (Callahan Trial Test., 347:17-20.)

Dr. Callahan also opined that the specific data of the CTFA survey demonstrated the study was not suitable for use in a scientific analysis of actual lipstick exposure. Dr. Callahan pointed out that the study included only 7 women of the relevant reproductive age in California – not enough to demonstrate statistical significance. (Callahan Trial Test., 179-180.) Dr. Callahan also identified that, even using all California subjects, their use rates varied unreliably – by a factor of 7 for the number of applications per day (from 1 to 7) and a factor of 400 for the weight of the total daily applications (from .005 to .2). (Callahan Trial Test., 63-64.) Dr. Callahan also opined that the lipstick use rates and amounts from the CTFA study were significantly underestimated and not suitable for use in an exposure assessment. (Callahan Trial Test., 69:11-21, 71.) Dr. Callahan based this opinion on the fact that 38% of the women in the study found the test lipstick to be worse than their normal lipstick, 30% did not like the test lipstick and 28% used the test lipstick less often than their normal brand. (Callahan Trial Test. 67:15-69:11.)

Dr. Callahan further identified that the CTFA data included alleged use amounts for certain users of .0011 grams per day achieved with a use rate of 6.5 applications per day. (Callahan Trial Test. 433-434.) Dr. Callahan explained that, at this rate, it would

take the user approximately 9 years and 21, 272 applications to finish a 3.6 gram tube of lipstick. (Callahan Trial Test. 433-434.) Dr. Callahan concluded that "[t]hese are unreasonable numbers, and I would say those data are unreliable and couldn't be used for any scientific study." (Callahan Trial Test., 324:5-8, 434:21-23.)

Dr. Callahan also provided the opinion that Dr. Lakin had incorrectly represented the data in his charts and opinions regarding alleged levels of exposure. Where Dr. Lakin used 4 applications per day as the 90% "upper bound" figure, Dr. Callahan pointed out that the CTFA data showed that almost 23% of the 18-39 year old study group, and 24% of the whole study group, used the lipstick more than 4 times per day. (Callahan Trial Test., 76:20-77:7). Dr. Callahan even pointed out that the EPA Exposure Factors Handbook used an upper bound figure of 6 applications per day – a figure the EPA specifically remarked was underestimated from including non-users in its averages and from problems with the survey groups. (Callahan Trial Test., 75:26-76:6, 436:26-437:10).

Where Dr. Lakin utilized .01 grams per application as a 90% "upper bound" figure, Dr. Callahan pointed out that the CTFA data, itself, showed that 27% of the 18-39 year old women used the test lipstick more than .01 grams per application. (Callahan Trial Test., 81:10-23.)

Where Dr. Lakin used a figure of .04 grams per day as his 90% "upper bound" amount of lipstick use, Dr. Callahan pointed out that the CTFA data demonstrated that 22% of the users used more than .04 grams per day. (Callahan Trial Test., 82:24-83:2.) Dr. Callahan also opined that risk assessment typically uses a 95% upper bound factor instead of 90%. (Callahan Trial Test., 84:18-19.) Dr. Callahan even used the CTFA average data to calculate the 95% upper bound of the average daily use of lipstick in the study. Dr. Callahan calculated that the 95% factor of average grams used per day by all 18-39 year olds in the study was .117 grams, by all women in California was .175 grams and by only 18-39 year olds in California was .202 grams – each significantly higher than the .04 grams per day represented by Dr. Lakin. (Callahan Trial Test., 178.)

Dr. Callahan further testified that she did not believe the European Economic report data was reliable because the report cautions readers not to use the data and to collect their own actual data on a case-by-case basis. (Callahan Trial Test., 324:5-8.)

5. Misleading or Deceptive Advertising Under B&P Code Section 17500

Dr. Mazis testified that in situations where consumers cannot determine the material characteristics of the product by themselves (such as the clock speed of a computer or the lead content of painted glassware or cosmetics) they especially rely on the seller of the products to provide them with such information.

Dr. Mazis testified that, in his opinion, the relevant "advertising" for determining whether a statement is untrue or misleading includes Defendant's entire marketing scheme for their product. This scheme is comprised of the totality of efforts by the Defendants and their employees in terms of traditional ads (whether print, radio or television), bill inserts, store ads, circular copies, point of sale signs, product displays (both at the individual product location and designated register, if applicable), salespersons, product brand awareness, brand image, retail store brand awareness/image, and product packaging. Dr. Mazis explained that of all of the marketing, the product packaging is usually the most significant interface with the consumer. Once each of these factors has been identified, it is appropriate to take all these together and look at the net general impression. In the context of misleading advertising, an actionable "omission" is simply a failure to include material information. Similarly, "materiality" in the context of misleading advertising, simply means that the omitted information would have an impact on the consumer's decision making or behavior toward the product, or the omitted information is likely to affect the consumer's choice of the product. In essence, a material omission occurs when the omitted information is important to the consumer. In considering the context of an actionable omission, it is also significant to consider whether there is no other easily available source for the omitted information regarding the product.

One such example of important omitted information is health risk information. Dr. Mazis described that this is always of high significance to consumer.

Dr. Mazis testified that his prior extensive experience in this field demonstrates that consumers are likely to read and retain packaging information regarding health and safety issues more than any other.

His own publications demonstrate that pregnant women are acutely concerned with health effects of known detriments to fetal health, such as alcohol, and that 95% of pregnant women will significantly change their behavior regarding exposure to such a harmful agent – with most pregnant women eliminating the harm altogether. Dr. Brown and Dr. Callahan generally testified as to the significance of consumer education about the potential for lead exposure for purposes of enabling the consumer to effectively reduce their own lead exposures and thus reduce their own risk. Dr. Lakin also testified extensively about the benefit of educating individuals about the potential for and risks of exposure to lead and other toxic substances. (Lakin Test., 9/23/03, 47-52). Dr. Lakin testified that, "by making the educational programs [about lead] available to the workers, one of the things [OSHA] found -- and has been found routinely by other programs that have done lead abatement, lead cleanup and, therefore, lead education -- is that people, rather dramatically, are able to affect their own blood lead levels by avoiding exposure." (Lakin Test., 9/23/03, 49:7-12). Dr. Lakin explained that, "for instance, that if you are told that you have dust in your house that has lead in it, which happens in paint abatement, and you're told how to clean that lead and avoid exposure, most people do that. And they very effectively reduce their own exposures, even though the lead, itself, the source, hasn't been cleaned up yet. They're better able to protect themselves. In fact, what OSHA found -- and I think they reported in a number of papers -- is that the workers' average exposure to lead did indeed drop not only from the workplace exposure changing, but probably also from their non-workplace exposure changing." (Lakin Test. 9/23/03, 49:13-24). Dr. Lakin also explained that "[c]ommunication is a very critical part of my profession's job in risk assessment. And one of the things that we absolutely find critical

is providing good, reliable information to people about what exposures they're receiving..." (Lakin Test., 9/23/03, 50:21-24). Finally, Dr. Lakin explained that because lead is ubiquitous, and everyone is exposed to lead to some degree, that "education is clearly going to help everybody reduce their overall lead exposure." (Lakin Test., 9/23/03, 52:1-5).

Dr. Mazis testified that reasonable consumers have certain expectations about the goods they purchase in stores. First, consumers expect that, if there is a toxin in a consumer product then the label will provide a warning or other indication of such presence and necessary precautions. Similarly, if there is no indication of a toxin on a label, the consumer will expect that there are no toxins in the product.

Dr. Mazis testified that retailers, to a limited extent, are "consumers" of products from the manufacturers and thus have certain expectations about what manufacturers will do. Dr. Mazis testified that retailers have a significant amount of leverage over the manufacturers or distributors from which they source their products. (Mazis Trial Test., 8/14/03). Dr. Mazis explained that it was his opinion that the sheer quantity of goods purchased by a retailer like J.C. Penney or Macy's West, and the potential prestige for a manufacturer/distributor to have their goods on sale at these stores, are other factors that give the retailer a considerable amount more power than the ordinary consumer to secure and police information about the quality of the goods being ordered. (Mazis Trial Test., 8/14/03).

Dr. Mazis opined that it would be unreasonable for a retailer to inquire of a manufacturer/distributor about lead content or consumer protection compliance of a product and then rely on an absence of any response to support a conclusion of an absence of an issue with respect to either inquiry. (Mazis Trial Test., 8/14/03). Instead the retailer should presume the worst until it could confirm to the contrary by specific, affirmative response from the manufacturer/distributor. (Mazis Trial Test., 8/14/03).

B. Defendants' Experts

1. Carla Kagel, Ph.D.

Dr. Kagel is an analytical chemist. She testified that the EPA Method 3050B (Exhibit E, solid digestion for metals), NIOSH Method 9100 (Exhibit D, surface lead wipe), and ASTM Method C927 (Exhibit C, lip and rim immersion in acetic acid) test methods used by Plaintiff were neither validated nor generally accepted for the purpose of showing exposure to lead from cosmetics and glassware, and she believed that blood lead testing was the only way to establish actual exposure to lead. Moreover, these methods tested for total lead, including all organic and inorganic compounds, as well as metallic (elemental) lead. Dr. Kagel did acknowledge that blood lead levels can detect wholesale changes in blood from lead exposure, but cannot differentiate the source of exposure from the myriad of potential exposures suffered by any given person – especially since the majority of the lead is going to be absorbed by bone and soft tissue. (Kagel Trial Testimony 9/9/03.) Dr. Kagel acknowledged that blood is not the "medium" to which any individual is ever exposed and would not be appropriate to identify the lead concentration in any given "medium" of exposure such as air, water, soil, food and and/or consumer products. (Kagel Trial Testimony 9/9/03.)

Dr. Kagel did not perform her own tests on any of the products, but reviewed the testing documents and testimony produced by Plaintiff. She testified that Plaintiff had not followed a sampling plan as required by Method 3050B, which made it impossible to assess the applicability of the results to other, non-tested products. Dr. Kagel testified that the 3050B digestion tests of cosmetics performed by Curtis & Tompkins were in the range of background lead (i.e., lead results of 5 ppm can be due to lead in the environment, and not necessarily in the cosmetics). Dr. Kagel testified that she had no evidence to suggest that there was contamination of the products tested by Curtis & Tompkins for Plaintiff. (Kagel Trial Testimony 9/9/03.) Dr. Kagel was not familiar with each product's chain of custody or the products' packaging. (Kagel Trial Testimony 9/9/03.) Dr. Kagel testified that the control blanks data she reviewed—laboratory analyzed for purposes of identifying

contamination or improper machinery calibration—were all within the acceptable range and showed no indication of any contamination. (Kagel Trial Testimony 9/8/03, 9/9/03.) The results were very close to the reporting limits for the tests, and those limits were unlikely to be accurate. (Kagel Trial Testimony 9/8/03 and 9/9/03.) As an analytical chemist, she testified that she relies upon validation data from a laboratory as indicia of reliability of the reported test results, and the lack of any validation data in the materials produced by Plaintiff made it impossible for her to rule out laboratory error or other causes of the reported low levels of lead in the cosmetics tested by Plaintiff. Dr. Kagel testified that she charges her clients for providing reports in a similar fashion as Curtis & Thompkins; without the "data validation" package. Dr. Kagel stated that this style of report is absolutely appropriate and she would not ordinarily prepare a data validation package herself unless specifically requested by the client, for an additional fee. (Kagel Trial Testimony 9/8-9/03).

Dr. Kagel believed that the amount of lead that would be released by the 3050B hot acid digestion exceeded the amount of lead that would be released from a cosmetic that was on the skin or in the stomach of a user, given the nature of the digestion. However, Dr. Kagel is not a toxicologist and did not offer an opinion on the way the cosmetic products might react with an individual during an instance of exposure. Although she did not have any first-hand observations of the testing, in her opinion, the types of problems associated with Plaintiff's tests and the results of those tests would be likely to overestimate the amount of lead in the cosmetics. Dr. Kagel did not examine any additional, independent testing data from the manufacturers of the cosmetics.

Dr. Kagel testified that the NIOSH 9100 wipe tests performed by Plaintiff were within the range of background (5 µg/wipe). The glasses had not been washed before they were wiped, and based on the documents from the laboratory, one cannot determine if the lead came from the paint on the glass or an external source, since lead is ubiquitous in the environment, including air and water. Dr. Kagel did not consider the equivalent lead concentrations for washed glassware. Also, the 9100 method is not validated to show

release of metals from a surface. Therefore, she opined that the results of Plaintiff's wipe tests did not show that lead was released from the painted surface of the glassware. The NIOSH 9100 method is accepted and adopted for use by the Federal government and was created and issued for the purpose of showing lead on the surface of objects. U.S. EPA and the CPSC expressly adopted NIOSH 9100 for demonstrating the leach of lead from surfaces (i.e. painted walls, mini-blinds, playground equipment, etc.). (Exhibits 135, 136).

Dr. Kagel testified that the C927 immersion tests performed by Plaintiff are subjective, and subject to potential laboratory error due to improper equipment or technique. Curtis & Tompkins modified the method by marking the 20 mm line with tape, and did not validate that modification to show that the results were accurate. It also modified the method by immersing glassware beyond the 20 mm line. However, Dr. Kagel did not know exactly the steps taken by Curtis & Thompkins in performing the glassware tests and Dr. Kagel did not identify specific laboratory error in the testing of the glassware. The results of a C927 test do not necessarily bear any relationship to the amount of lead that could reasonably be released from a glass through normal use. Dr. Kagel did not study the type of beverages that might be used in a glass, including juice or wine, nor did she study Dr. Brown's wash and wipe test.

2. Michael L. Lakin, Ph.D., DABT

Dr. Lakin is a board-certified toxicologist, who has extensive experience in risk assessment and Proposition 65 exposure assessments. Dr. Lakin testified regarding exposure to lead from cosmetics. Dr. Lakin testified that Plaintiff had not shown an exposure to lead from cosmetics. First, he testified that the 3050B Method is not specific to the lead listed under Proposition 65, which is limited to the OSHA listing of metallic lead, inorganic lead, and organic lead soaps, and does not itself meet the requirements of 22 Cal. Code Regs. § 12901. Dr. Lakin acknowledged the FSOR for § 12805 providing the MADL for lead does not reference any limitation on what constitutes "lead", nor does the listing of the chemical itself. Dr. Lakin admitted that compounds of lead, inorganic and organic alike, contain the same elemental lead, and breakdown to the same elemental

lead. Second, any lead that is in the cosmetic would be in a matrix, and no tests had been performed to show that the lead was available to penetrate the skin or be absorbed in the stomach. Dr. Lakin did not do any research into the chemicals in the lipstick formulation or how those chemicals bonded together to otherwise for a "matrix." Third, lead on the skin is not an exposure to lead from a toxicological perspective, because there has been no demonstration that the lead is or can penetrate the skin, and "contact" with a boundary to a toxicologist (as the word "contact" is used in 22 Cal. Code Regs. § 12102 (i)) means communication with the boundary). In order for lead to cause reproductive effects it must enter the bloodstream, and the only validated and generally accepted method of demonstrating exposure to lead is by measuring blood lead. Dr. Lakin based his opinion of dermal absorption of inorganic lead on dermal absorption factors utilized in government "lead spread models", on a research paper published in 1988, and the EPA dermal absorption guidance document. As for blood lead levels, they do not distinguish between "old lead" that is being released from bone and "new lead." In Dr. Lakin's opinion, there was no evidence from which one could determine that any lead in cosmetics was capable of crossing, or in fact did cross, the skin, or was ingested or absorbed through the ocular area. Dr. Lakin had not studied the structure of the eye with respect to absorption of lead. Dr Lakin acknowledged that the conjeunctiva, or inner eyelid, was highly vascularized and had no protective lipid layer to withstand absorption of the lead in makeup. (Lakin Trial Testimony 9/28-9/30/03.) Dr. Lakin also admitted that the naso-lacrimal gland functioned like a giant drain to bring materials contacting the eye or eyelid down into the nasal passage, mouth and stomach—all the way along another highly vascularized wall of easily penetrable epithelial cells. (Lakin Trial Testimony 9/28-9/30/03.)

Dr. Lakin testified that, assuming the lead tested by Plaintiff was the chemical listed under Proposition 65, and that Plaintiff's tests data in fact showed lead (i.e., was reliable), the amount of lead in the cosmetics did not exceed the level that required a warning under Proposition 65. Dr. Lakin performed a theoretical upper bounding estimate

("TUBE") to assess the potential magnitude of the exposure. Following the safe harbor approach of 22 Cal. Code Regs. § 12821, as explained in the Final Statement of Reasons (FSR) for Article 8 of the Proposition 65 implementing regulations (Exhibit G), he compared the reasonably anticipated rate of intake or exposure, (based on product usage data and lead content) with the Maximum Allowable Daily Level (MADL) of 0.5 µg /day for lead established by 22 Cal. Code Regs. § 12805(b). He relied upon Plaintiff's test data for the amount of lead in cosmetics, which he believed was likely to overestimate actual exposure due to the acid digestion. He relied, based on guidance in § 12821, upon product usage information from the EPA Exposure Factors Handbook (Exhibit 4Ms), the CTFA Study of lipstick usage (Exhibits 40s and 5Gs), and the European Union Notes of Guidance for Testing of Cosmetics Ingredients for Their Safety Evaluation (Exhibit 4Ns), to estimate the amount of product used by average users of the cosmetic products.

Based on these data, the amount of lead placed on the skin of the user for any individual product within a cosmetic kit, and for a worst-case use of all tested products in any cosmetic kit, did not exceed 0.5 µg/day, whether the user was an average user, or in the upper 90th percentile of all users. Dr. Lakin testified that it would not be proper to include all exposures to lead from the various components of the cosmetic kits in one exposure assessment, because the products were not necessarily used together by the average user; however, including all of the products did not cause the amount of lead applied to the skin to exceed 0.5 µg/day.

Dr. Lakin testified that standard toxicological exposure assessment principles required the analysis of actual absorption of lead through the skin and stomach. These principles were consistent with Proposition 65's implementing regulations as described in the "pattern and duration of exposure" in § 12821 and with guidance in the Final Statement of Reasons that indicated it was appropriate for absorption to be considered in determining whether an exposure posed no observable effect within the meaning of Proposition 65. Dr. Lakin testified that it would not be inappropriate to apply absorption to different routes of exposure to lead when using the 0.5 µg/day MADL, as that MADL

had been developed based on inhalation data only, and lead was absorbed very poorly, if at all, by dermal contact, and at ranges of 6-10% by ingestion under average conditions, compared with very efficient absorption of lead when inhaled. Dr. Lakin testified that there was no prohibition in the regulations or Final Statement of Reasons against applying route-specific absorption data, and that the California Environmental Protection Agency Office of Health Hazard Assessment (OEHHA) had changed its practices to do so when adopting MADLs in light of a recommendation from a peer-review of its risk assessment practices in the mid-1990s (approximately 10 years after the lead MADL had been adopted). When Dr. Lakin included the standard absorption factors used by Cal/EPA and federal EPA, the amount of lead exposure he calculated from the cosmetics was at least 1000 times below the MADL for all products within a kit.

Dr. Lakin did not test any cosmetic products, as the Plaintiff's test results were orders of magnitude below the warning level, and there was no reason to believe that further testing would result in significantly elevated exposures. Dr. Lakin rejected the after-the-fact argument that Plaintiff's test results were inaccurate and underestimated the total amount of lead in the products.

Dr. Lakin testified that exposure to lead is not properly assessed on a one-day basis, because it is not a teratogen. Toxicologists, and California state agencies, typically assess lead exposure on a 30-day average exposure, because the reproductive effects for which it is listed are based on chronic exposure. For purposes of his assessment, he assumed that the exposures he calculated were occurring every day. Dr. Lakin testified that the amount of lead to which a women would be exposed would not be detectable in her blood. He also testified that the products posed no danger to users from any lead that was contained in them.

3. James W. Embree, Ph.D., DABT

Dr. Embree is a board-certified toxicologist, who has extensive experience in risk assessment and Proposition 65 exposure assessments. Dr. Embree testified regarding exposure to lead from painted glassware. Dr. Embree testified that Plaintiff had not

shown an exposure to lead from cosmetics, because Plaintiff had not tested for the specific listed chemical in the specific medium, as is required under 22 Cal. Code Regs. § 12901. Dr. Embree performed some testing of paint on glassware, but it did not change his opinion that Plaintiff did not test for the listed chemical for the specific medium.

Dr. Embree testified that the ASTM C927 Method does not show an exposure to lead from glassware, as it is not validated to do so, and the method specifically states that it does not represent actual conditions of use. Dr. Embree acknowledged FDA comment that the C927 voluntary testing program "will ensure that the public is not presented with any significant health risk due to lead . . . that may leach from decorated glass tumblers." (Ex. 4D, p. 58633.) Although he did not observe the Curtis & Tompkins testing for Plaintiff, his own pilot testing with acetic acid led him to believe that there were potential problems with the tests performed by Curtis & Tompkins. These potential problems included the improper equipment used to perform the test and the possibility of contamination or disturbance of the samples while the test was being performed. His own pilot testing with artificial saliva led him to conclude that acetic acid immersion for 24 hours did not provide any realistic assessment of whether lead leached from the glassware under normal conditions of use. Dr. Embree admits his protocol is experimental and does not establish an approved scientific methodology for lead leaching from paint on a glass. Dr. Embree did not take account of the possible acidity of the beverage being consumed on the exterior rim, which may have a similar acidity to the leaching solution used in the C927 Method. The use of the C927 Method did not meet § 12901 because it is not specific to the listed lead, but tests for all lead, and the medium tested is acetic acid, which is not the medium to which the user is exposed.

Dr. Embree acknowledged that the NIOSH 9100 wipe test is a federally created standard adopted for identifying the surface presence of chemicals on an object. However, Dr. Embree testified that the NIOSH 9100 wipe tests did not show an exposure to lead from glassware for several reasons. First, the method is not validated to show exposure to lead leaching from a surface, as it is only validated to show environmental

contamination of lead. Since Plaintiff had not washed the glasses before testing them, there was no basis to conclude that the lead in the tests came from the paint on the glass. Second, the method is not specific for the listed lead, but tests for all lead, and the medium tested is the lead itself on the surface of the glass.

In Dr. Embree's opinion, from a toxicological perspective, the medium of concern is that which carries the chemical to the body. Thus, the media to which the user was exposed to lead that might be released from the painted glass surface could be the saliva (in the case of direct contact) or the object to which the lead was supposedly transferred, such as a piece of bread (in the case of indirect contact). FSOR for 22 CCR § 12821 defines the "medium" as a certain type of food or a consumer product, but that the exposure from a given medium will depend upon the medium, its anticipated use and other circumstances. (Exhibit G, pg. 83). Dr. Embree testified that the medium at issue in this case is not the product, because the user is not actually ingesting the product. Because there was no method that met the requirements of § 12901, in his opinion there was no showing of exposure to lead from the products. While acknowledging that NIOSH 9100 and ASTM C927 are adopted by both State and Federal governments, Dr. Embree, as with Dr. Lakin, testified that the only validated and generally accepted method of demonstrating exposure to lead is by measuring blood lead.

Dr. Embree testified that, even assuming that the tests showed the listed chemical, because the various potential media of exposure had not been identified or tested, there was no method that met the requirements of § 12901 that would allow for the quantification of the amount of lead to which average users were exposed. If he was forced to accept Plaintiffs tests as demonstrating an exposure (thus meeting § 12901), then he opined, in his professional judgment, that the user would only ingest approximately 5% of the total amount wiped off of a glass with the modified NIOSH 9100 methodology. Dr. Embree agreed that this 5% "guesstimate" was just a personal, professional judgment. This judgment was not made to any reasonable degree of scientific validity or certainty; not based upon any scientific study or principle. Dr. Embree did not analyze the hand-to-

mouth ingestion and he rejected both the CPSC's 50% figure from the mini-blinds experiment and the CPSC's 43% figure from the playground equipment investigation, as well as the EPA's Exposure Factors Handbook's reported comparison of the hand-to-mouth ingestion rates between children and adults of 50%. In analyzing his modified test, Dr. Embree concluded that not all lead transferred to the hands would ultimately be ingested, and then premised his quantification estimate on several grounds including, (a) the pad used to wipe the glass was more abrasive than a finger; (b) fingers of the user would not contact the entire surface of the decoration, in contrast to the wipe, which was intended to cover the entire surface area (Dr. Embree did no investigation into how a normal user would use the glass, where they might contact it, whether any contact might involve rubbing the surface of the paint, the length of duration of the contact or the temperature and content of the glass.); (c) the handling of the product when it was used by the consumer; and (d) any lead transferred from the glass to the fingers could remain on the fingers, be transferred to an object and never enter the mouth, be transferred back to the glass, or be transferred directly or indirectly to the mouth.

In Dr. Embree's opinion, any glass with wipe test results of 10 µg/wipe would meet the 0.5 µg/day MADL. The estimate did not take into account any absorption of lead from the digestive tract; however, Dr. Embree testified that the relatively poor absorption of insoluble inorganic lead in the digestive tract would decrease the actual exposure to the user by 90%, based on data for such lead in the Agency For Toxic Substances ATSDR Toxicological Profile for lead. Dr. Embree had no specific information on what species of lead was present in the paint. He also had no information on solubility, except that he believed that the lead was inorganic and soluble because the glass would be washed before use. Dr. Embree testified that the use of absorption data was a principle of toxicological risk assessment, and was specifically identified as appropriate under the FSR for Article 8, including for ingestion of lead. As with Dr. Lakin, Dr. Embree testified that it would not be inappropriate to apply absorption to different routes of exposure to lead when using the 0.5 µg/day MADL, and there was no

prohibition in the regulations or Final Statement of Reasons against applying route-specific absorption data to the MADL. When applying this standard absorption factor, any wipe result of 100 µg or less would not exceed the 0.5 µg/day MADL.

Dr. Embree did not average a user's exposure over multiple days, although he believed it would be appropriate to do so for the purposes of chronic exposure analysis to lead. For purposes of his assessment, he assumed that the exposures he calculated were occurring every day. He also testified that, assuming exposure to the amount of lead in a wipe test, such exposure would not be detectable in the bloodstream of the user. He also testified that the products posed no danger to users from any lead that was contained in them.

4. David Stewart, Ph.D.

Dr. Stewart is a Professor of Marketing, and Deputy Dean of the Marshall School of Business, at the University of Southern California. Dr. Stewart testified that whether an omission is material depends on whether conveying the information will change the reasonable consumer's behavior. He testified that studies suggest that consumers don't think in terms of levels of chemicals, but is this a safe product, and should I exercise caution? Consumers look to experts to set standards in certain situations. In Dr. Stewart's opinion, it is not misleading to not warn about exposures to chemicals that are not potentially harmful. And, in the absence of any proof that products are potentially dangerous, the presence of lead is not "material" to an ordinary consumer, and it is therefore not misleading to omit identification of lead in the product. (Stewart Trial Testimony 10/7/03).

As he understands that lead is ubiquitous in the environment, Dr. Stewart testified that there are potential adverse impacts from Plaintiff's disclosure theory. Warnings about lead in non-harmful amounts may deluge consumers and drown out important warnings. Warnings may cause consumers to forego benefits from presence of lead (e.g., certain colors in glassware) without any increase in safety. A warning in the

circumstances of this case is potentially misleading to consumers, given the lack of potential harm from the products, and these other factors.

Dr. Stewart testified that it would be inappropriate to determine the need for warnings based on the aggregate risk posed by all of the products within a kit, as opposed to the individual products. Manufacturers typically bundle products together because consumers are likely to use those products together, but if the individual products are dangerous only in combination, the activity that needs to be addressed is the lifestyle choice of the user, not the way in which the products are packaged. Warnings on "kits" that are based on aggregation of risk from individual products will drive consumers to the same products separately-sold and individually-packaged, and will create no health benefit, because the consumers are subject to the same risk from the aggregate use of the individual products.

Dr. Stewart did not generally know whether the majority of the cosmetic kits contained components that were available for individual sale. Dr. Stewart acknowledged that B&P Code § 17500 does not concern itself with potential adverse impacts, only whether the consumer is likely to be misled. Dr. Stewart agreed that the relevant standard is whether the omitted information would affect a consumer's decision to purchase the product.

V. EVENTS AFTER THE FILING OF THE NOTICES AND COMPLAINTS

A. Macy's West's Actions Following Receipt of Notice for Cosmetics

On November 20, 2001, Plaintiff served Macy's West with a 60-Day Notice of alleged violation of Proposition 65 for selling certain cosmetic kits containing lead without a clear and reasonable warning. *See* Exhibit 91. The notice specifically identified the products at issue as "COSMETIC KITS" and further referenced, as specific examples, "The Color Institute Spring Beauty" and "The Color Institute Color Ensemble" cosmetic kits, manufactured by Markwins. The notice identified Markwins as the "manufacturer" of the products at issue.

Ms. Morello, Ms. Barr and Ms. Campbell all testified that they had never heard anything about lead being in any cosmetic products prior to receipt of Mr. DiPirro's 60-Day Notice alleging consumer exposures to lead from cosmetics. Macy's West's representatives did not contact vendors for the purpose of confirming whether or not the vendor's cosmetics contained lead. The representatives did not consider suspending the sale of the products identified in the Notice. (Barr Trial Testimony 9/10/03, 9/30/03; Campbell deposition testimony at 52:21-25).

After receiving the 60-day notice, counsel for Macy's West contacted Markwins regarding the notice and tendered the defense of Macy's West on or about November 28, 2001. (Exhibit 6Ws.) Markwins never responded to the tender letter. Macy's West did not follow up on the letter, but soon learned that, on December 21, 2001, Markwins entered into a settlement with Plaintiff that covered cosmetic kits and provided a downstream release for its retailers. (Exhibit 95.) The Consent Judgment specifically provided that Markwins agreed to a Reformulation Commitment as follows: "**1.1 Reformulation Timetable.** Beginning immediately, Markwins shall initiate or otherwise arrange for diligent efforts to be undertaken to revise the Product's formulations so as to *eliminate the presence of lead*, as that phrased is defined in paragraph 1.4, below. As of July 31, 2002, Markwins agrees not to manufacture or sell (or cause to be manufactured or sold on its behalf) any of the Products unless each such Product has been manufactures so as to *eliminate the presence of lead*, as that phrase is defined in paragraph 1.4, below....**1.4 Lead Content**. Through reformulation, Markwins intends to completely *eliminate the presence of lead* in the Products. Markwins asserts, however, that it may be impossible to remove all detectable amounts of lead from the Products. Therefore, for purposes of this Settlement Agreement, the *presence of lead* shall be deemed to be eliminated in the Products according to the following schedule: 1) no lipstick shall contain greater than .35 parts per million (ppm) of lead; and 2) no other cosmetic item, including eyeshadows and blushes, shall contain greater than .5 parts per million (ppm) of lead. Markwins shall use EPA testing methodology 6020 or 6010 to determine whether the respective levels have

been exceeded in their cosmetic products. The parties agree that Markwins may modify the test method so long as: 1) the method is appropriate under 22 CCR § 12901; and 2) DiPirro is provided 30 day written notice of the requested modification. Consent by DiPirro to such modification shall not be unreasonably withheld." (Emphasis in original.) The Consent Judgment further expressly provided that "[n]othing in this Agreement shall be construed as an admission by Markwins of any fact, finding, issue of law, assertion, allegation or violation of law, nor shall compliance with this Agreement constitute or be construed as an admission by Markwins of any fact, finding, conclusion, issue of law, or violation of law." (Exhibit 95). After receipt of the complaint, Macy's West's counsel contacted counsel for Markwins regarding the tender letter and the allegations contained in the complaint. Markwins' counsel informed Macy's West in May of 2002 that they did not respond to the tender because Markwins had settled the matter with Plaintiff in December 2001. (Brandt Trial Testimony, 10/14/03; Exhibit 95.)

On May 2, 2002, Plaintiff filed his complaint against Macy's West. (Exhibit 6Es.) The complaint offered no additional information with respect to the nature and extent of the alleged violations as set forth in the 60-day notices. Upon receipt of the lawsuit, Ms. Brandt attempted to contact the counsel listed on the original 60-Day Notice, David Bush. Mr. Bush's office referred Ms. Brandt to counsel of record Gregory Sheffer. Ms. Brandt contacted Mr. Sheffer in June 2002 in an attempt to ascertain which cosmetic kits were at issue in the lawsuit in light of the Markwins settlement. Mr. Sheffer referred Ms. Brandt to his partner Clifford Chanler. Ms. Brandt instructed outside counsel, Jeffrey Margulies to contact Mr. Chanler to determine exactly what products were at issue in the DiPirro lawsuit. (Brandt Trial Testimony, 10/14/03.) Mr. Margulies contacted Mr. Chanler on or about May 23, 2002 and requested the following clarification on the products at issue: "Cliff, as we discussed recently, the only product named in the 60-day notice served on Macy's West was the Markwins cosmetic kit. The complaint names 'cosmetic kits containing eye shadows, blushers, lipsticks, lipliners and/or nail polishes,' but as I have remarked, Macy's West has no idea what products are involved, which

vendors to notify, or even how to respond to this complaint. Please advise which, if any, products other than the Markwins products you believe that Macy's sold an contain lead as alleged in the complaint." Mr. Chanler responded on May 24, 2003, via email, as follows: "There are other cosmetic product with lead. Sorry for the delay; I will get you the information early next week." (Exhibit 1022). Mr. Margulies followed up on this communication on or about June 6, 2002, but no further cosmetic kits were identified by Mr. Chanler. (Brandt Trial Testimony, 10/14/03; Exhibit 1022.)

Ms. Brandt sent a tender letter on July 31, 2002 to all of Macy's West's cosmetics vendors. The letter indicated that the vendor's products might be implicated but that Macy's West did not have enough information. ("The complaint fails to specify the brand name of the cosmetic product(s) at issue, and therefore we are tendering this matter to each of the vendors that we do business with that manufacture eye shadows, blushers, lipsticks, lip liners, and nail polish.") (Exhibit 6X's). The letter further requested that the vendors confirm that their products comply with all laws, specifically Proposition 65, and inform Macy's West if their products did not comply, so that appropriate action could be taken. ("Federated will not knowingly offer for sale in California products that do not comply with Proposition 65... Please send me a letter confirming that your products comply with Proposition 65... Should you learn at any point in the future that your products do not comply with Proposition 65, you must immediately notify Federated so that appropriate action may be taken.") (Brandt Trial Testimony, 10/14/03; Exhibit 6Xs.) No cosmetic vendor indicated that their products did not comply with Proposition 65 or that their products exposed consumers to lead. (Exhibit 6Ys.) Ms. Brandt did not follow-up on the tender letters or her request regarding compliance with Proposition 65. Later, Shisheido and Loral specifically affirmed that their products complied with Proposition 65. (Brandt Trial Testimony, 10/14/03.) Ms. Brandt testified that no vendor had agreed to or made any financial contribution pursuant to Macy's West's letter.

Macy's West filed a Demurrer on June 6, 2002, which came on for regular hearing on July 18, 2002. This Court found that the Plaintiff's "60-Day Notice", and the ensuing

Complaint, adequately complied with all of the notice requirements of California Health & Safety Code, Section 25248.7, such as to give Defendant adequate description of the products at issue and adequate notice of Plaintiff's claims against them. Based upon these and other findings, Macy's West's Demurrer was overruled. On October 21, 2002, Defendants filed their petition for writ of mandate contesting the ruling on Demurrer. On November 7, 2002, the First Appellate District denied Defendants' petition for writ of mandate without comment.

Because Macy's West did not receive any information from its vendors that identified which products contained lead, on September 6, 2002, Macy's West served special interrogatories on Plaintiff requesting, *inter alia*, that Plaintiff identify any cosmetic kits sold by Macy's West that allegedly contained or exposed users to lead, other than those manufactured by Markwins. (Exhibit 6Fs.) Plaintiff's initial response to Macy's West's discovery did not identify any additional cosmetic kits and merely referred Macy's West to the 60-Day Notice. (Exhibit 6Gs.) Following a meet and confer process, Plaintiff agreed to supplement his responses to Macy's West's discovery, however, his supplemental responses did not identify any additional cosmetic kits and referred, again, to the 60-Day Notice. (Exhibit 6Hs.) Macy's West filed a Motion for Summary Judgment on December 24, 2002, contending that there was no triable issue of fact, since Plaintiff had released Macy's West from liability for sale of Markwins products as a result of his settlement with Markwins, was limited to the Markwins products by his 60-day notice, and had failed to identify any other allegedly violative cosmetic kits. After a continuance to allow Plaintiff to conduct discovery, that motion was heard on June 23, 2003, and denied in an order dated September 8, 2003.

On January 27, 2003, Plaintiff served his second supplemental responses to Macy's West's first set of discovery. (Exhibit 6Is.) In the second supplemental responses, Plaintiff identified cosmetic kits distributed by Fashion Fair for the first time. Fashion Fair had been sent one of the original tender letters, but had never responded. (Brandt Trial Testimony, 10/14/03). On February 5, 2003, the deposition of Plaintiff Michael

DiPirro was taken but no additional cosmetic kits were identified as being at issue in the lawsuit other than those previously identified in discovery responses. On February 14, 2003, Macy's West sent follow-up correspondence to Fashion Fair informing them that Plaintiff has specifically identified their products as containing and exposing users to lead. (Exhibit 99.) On March 24, 2003, Fashion Fair sent correspondence to Macy's West forwarding test results indicating the presence of lead in some of the components of the Beauty on the Go and Glitter 'N Go products. (Brandt Trial Testimony, 10/14/03; Exhibit 99, p. 1262). In Plaintiff's fourth supplemental responses to Macy's West's first set of discovery, served on April 21, 2003, Plaintiff identified an additional cosmetic kit, Christian Dior's Esprit De Bruns. (Exhibit 6Ks.) Plaintiff for the first time produced summary lead testing results with his fourth supplemental interrogatory responses. Follow-up correspondence was sent to Christian Dior but Macy's West never received any information from the vendor regarding lead in cosmetics before Ms. Brandt took her maternity leave shortly before trial in June 2003. (Brandt Trial Testimony, 10/14/03.)

Plaintiff did not produce documents identifying the laboratory testing of the cosmetics until after the commencement of trial, claiming that discovery prior to that time was precluded by the work product doctrine.

On May 31, 2002, Plaintiff propounded his First Set of Special Interrogatories to Macy's West. Interrogatory No. 1 requested that, in response to a request for the total unit quantity of products sold, Macy's West identify cosmetic kit sold by brand name, product name and product description. Defendant's responses to this discovery request did not identify any products sold by Macy's West. Macy's West responded with a global objection to Plaintiff's definition of "PRODUCTS", in that, "it requests information about products not sufficiently identified in Plaintiffs 60-day notice, and thus seeks information that is NOT RELEVANT." In response to a PMK deposition notice, Macy's West designated the following people: Elizabeth Morello, Carye Campbell and Jill Barr. Plaintiff objected that the witnesses were not qualified witnesses in that they had not done a sufficient investigation and were not knowledgeable. Plaintiff served additional

discovery on March 13, 2003, seeking, among other things, product identification. On June 5, 2003, at a hearing before Commissioner Norris on Defendants' Motion for a Protective Order, Plaintiff was ordered to designate up to 50 interrogatories for Macy's West to answer. Defendants' June 30, 2003 responses did not identify any cosmetic kits sold by Macy's West pending a ruling on their Motion for Summary Judgment. (On July 15, 2003, Plaintiff made an Ex Parte Application to have his Motion to Compel heard on shorten time, a motion that Commissioner Norris denied.)

At the beginning of trial, Plaintiff served discovery on both Defendants in the form of Special Interrogatories and Requests for Production. Defendants objected to the breadth and form of the trial discovery. On July 31, 2003, the Court made the following orders regarding discovery: (a) the Defendants were ordered to respond in part to the discovery, (b) the term "cosmetic kit[s]" in the definition of the term "PRODUCTS" in each Interrogatory No. 1, respectively, for purposes of this discovery, shall mean a collection of separate cosmetics packaged and/or sold together from three or more of the following six categories: (1) lipstick, (2) lip liner/lip pencil, (3) eye shadow, (4) mascara, (5) blush/facial powder and (6) eye liner/eye pencil; (c) Defendants shall provide a report advising the Court of the date on which sales data for the products sold in California in response to each Interrogatory No. 2 can be produced; and (d) to the extent that Defendants claim attorney-client and/or attorney work product as an objection to information sought in the interrogatories or requests for production, Defendants shall produce a privilege log of any information withheld, excluding only information created by or sent to or from trial counsel for Defendants, Jeffrey B. Margulies, Esq. and Rachel D. Stanger, Esq. of Parker, Milliken, Clark, O'Hara and Samuelian (and/or predecessor counsel for J.C. Penney), after the Complaints were filed in each of these consolidated cases, respectively.

Defendant Macy's West served responses to Plaintiff's first set of trial discovery on August 7, 2003. The responses identified all products that met the definition of "cosmetic kit" as determined by the Court. The majority of the products identified were

Gifts with Purchase and Purchases with Purchase. No evidence was presented at trial demonstrating that any of the products identified in the responses to trial discovery contained lead.

B. J.C. Penney's Actions Following Receipt of Notice for Cosmetics

On October 11, 2000, Plaintiff served J.C. Penney with a 60-Day Notice of alleged violation of Proposition 65 for selling certain cosmetic kits containing lead without a clear and reasonable warning. See Exhibit 92. The notice specifically referenced the products at issue as "Eyeshadows, Blushes, Cosmetic Kits" and provided an example of such products by including the parenthetical phrase, "such as Markwins' Wings of Beauty cosmetic kits." After receipt of the 60-day notice pertaining to cosmetics, J.C. Penney joined a joint defense group that included Markwins and other retailers that had received similar notices in October – November 2000. Prior to receipt of the lawsuit, J.C. Penney did not discuss lead in cosmetics with any vendors other than Markwins. J.C. Penney never received any test results for Markwins' cosmetics. (Harokopus Trial Testimony, 11/6/03). On December 21, 2001, Markwins entered into a settlement with Plaintiff that covered cosmetic kits and provided a downstream release for its retailers. (Exhibit 95.) The Consent Judgment specifically provided that Markwins agreed to a Reformulation Commitment as follows: "**1.1 Reformulation Timetable.** Beginning immediately, Markwins shall initiate or otherwise arrange for diligent efforts to be undertaken to revise the Product's formulations so as to *eliminate the presence of lead*, as that phrased is defined in paragraph 1.4, below. As of July 31, 2002, Markwins agrees not to manufacture or sell (or cause to be manufactured or sold on its behalf) any of the Products unless each such Product has been manufactures so as to *eliminate the presence of lead*, as that phrase is defined in paragraph 1.4, below....**1.4 Lead Content.** Through reformulation, Markwins intends to completely *eliminate the presence of lead* in the Products. Markwins asserts, however, that it may be impossible to remove all detectable amounts of lead from the Products. Therefore, for purposes of this Settlement Agreement, the *presence of lead* shall be deemed to be *eliminated* in the Products according to the

following schedule: 1) no lipstick shall contain greater than .35 parts per million (ppm) of lead; and 2) no other cosmetic item, including eyeshadows and blushes, shall contain greater than .5 parts per million (ppm) of lead. Markwins shall use EPA testing methodology 6020 or 6010 to determine whether the respective levels have been exceeded in their cosmetic products. The parties agree that Markwins may modify the test method so long as: 1) the method is appropriate under 22 CCR § 12901; and 2) DiPirro is provided 30 day written notice of the requested modification. Consent by DiPirro to such modification shall not be unreasonably withheld." (Emphasis in original.) The Consent Judgment further expressly provided that "[n]othing in this Agreement shall be construed as an admission by Markwins of any fact, finding, issue of law, assertion, allegation or violation of law, nor shall compliance with this Agreement constitute or be construed as an admission by Markwins of any fact, finding, conclusion, issue of law, or violation of law." (Exhibit 95).

After receipt of the Notice, neither Ms. Bokar nor Ms. Parker contacted the cosmetic vendors to determine if their products contained lead. No further activities occurred with respect to the cosmetics notice until April 25, 2002, when Plaintiff filed his complaint against J.C. Penney. The complaint offered no additional information with respect to the nature and extent of the alleged violations as set forth in the 60-day notices. After the complaint was filed, J.C. Penney did not investigate through it RTL or inquiry of vendors whether the cosmetic products contained lead. After receipt of the complaint, on June 12, 2002, J.C. Penney sent correspondence to its cosmetic vendors tendering the defense and indemnity of J.C. Penney for the lawsuit. (Exhibit 36.) The tender letters did not inquire if the cosmetics products contained lead, nor did J.C. Penney test the cosmetics for lead due to RTL's unfamiliarity with cosmetics testing and inability to perform tests on cosmetics. Specifically, the tender letters stated, in pertinent part, as follows: "...The Notice and Complaint allege that J.C. Penney and its suppliers failed to warn such persons of possible exposure, caused by the use of eyeshadows, blushers and cosmetic kits it sells, to chemicals know to the State of California to cause cancer or

reproductive toxicity. Because your company supplies J.C. Penney with products that are the subject of the enclosed Notice and Complaint, J.C. Penney hereby tenders this matter to you for defense and indemnification....We respectfully demand a prompt response from the appropriate person in your organization, so that we may address this situation before incurring significant legal fees. Please let us know at your earliest opportunity how you wish to proceed." The tender letters were sent to the following vendors: Rivera, Inc., Avon, Color Me Beautiful, Revlon, Inc., Fashion Fair, and Markwins International. (Exhibit 36). Throughout June 2002, J.C. Penney received responses to its tender letters, and other communications, from a number of its cosmetic vendors, including Private Portfolio/Riviera Concepts, Fashion Fair and Revlon. (Exhibits 1012, 1013.) No vendor indicated that its products did not comply with Proposition 65. No vendor indicated that its products exposed consumers to lead.

J.C. Penney filed a Demurrer on June 11, 2002, which came on for regular hearing on July 18, 2002. This Court found that the Plaintiff's "60-Day Notice", and the ensuing Complaint, adequately complied with all of the notice requirements of California Health & Safety Code, Section 25248.7, such as to give Defendant adequate description of the products at issue and adequate notice of Plaintiff's claims against them. Based upon these and other findings, J.C. Penney's Demurrer was overruled. On October 21, 2002, Defendants filed their petition for writ of mandate contesting the ruling on Demurrer. On November 7, 2002, the First Appellate District denied Defendants' petition for writ of mandate without comment.

On September 23, 2002, J.C. Penney served Special Interrogatories on Plaintiff requesting, inter alia, that Plaintiff identify any cosmetics sold by J.C. Penney that allegedly contained or exposed users to lead, other than those manufactured by Markwins. (Exhibit 60s.) Plaintiff's initial response to J.C. Penney's discovery did not identify any additional cosmetic kits and merely referred to the 60-Day Notice. (Exhibit 6Ps.) Following a meet and confer process, Plaintiff agreed to supplement his responses to J.C.

Penney's discovery, however, his supplemental responses did not identify any additional cosmetic kits and referred, again, to the 60-Day Notice. (Exhibit 6Qs.)

J.C. Penney filed a Motion for Summary Judgment on December 24, 2002 contending that there was no triable issue of fact, since Plaintiff had released J.C. Penney from liability for sale of Markwins products as a result of his settlement with Markwins, was limited to the Markwins products by his 60-day notice, and had failed to identify any other allegedly violative cosmetic kits. After a continuance to allow Plaintiff to conduct discovery, that motion was heard on June 23, 2003, and denied in an order dated September 8, 2003.

On January 27, 2002, Plaintiff's second supplemental discovery responses identified the following additional cosmetic kits sold by J.C. Penney that allegedly contained lead: Luxurious Traincase, Riviera Concept's Inc.'s Professional Blockbuster kit. (Exhibit 6Rs.) On April 21, 2003, Plaintiff's fourth supplemental discovery responses identified Sheer Halston The Holiday Evening Accessory Collection; and IMS Industry Color Impact the Cool Bag. (Exhibit 6Ss.) Plaintiff for the first time produced summary lead testing results with his fourth supplemental interrogatory responses. On May 1, 2003, Plaintiff's supplement to his fourth supplemental interrogatory responses identified Elizabeth Taylor Passion the Holiday Evening Collection. (Exhibit 6Ts.).

Plaintiff did not produce documents identifying the laboratory testing of the cosmetics until after the commencement of trial, claiming that discovery prior to that time was precluded by the work product doctrine.

On June 2, 2002 and June 3, 2002, Plaintiff propounded his First and Second Sets of Special Interrogatories to J.C. Penney regarding cosmetic kits and painted glassware, respectively. In these sets, Interrogatory No. 1 requested that, in response to a request for the total unit quantity of products sold, J.C. Penney identify the cosmetic kits or painted glassware sold by brand name, product name and product description. Defendant's responses to this discovery request did not identify any such types of products sold by J.C. Penney. J.C. Penney responded with a global objection to Plaintiffs definition of

"PRODUCTS", in that, "it requests information about products not sufficiently identified in Plaintiff's 60-day notice, and thus seeks information that is NOT RELEVANT." Plaintiff served additional discovery on March 13, 2003, seeking, among other things, product identification. On June 5, 2003, at a hearing before Commissioner Norris on Defendants' Motion for a Protective Order, Plaintiff was ordered to designate up to 75 interrogatories for J.C. Penney to answer. Defendants' June 30, 2003 responses did not identify any cosmetic kits sold by Macy's West pending a ruling on their Motion for Summary Judgment. (On July 15, 2003, Plaintiff made an Ex Parte Application to have his Motion to Compel heard on shorten time, a motion that Commissioner Norris denied.) In response to a PMK deposition notice, J.C. Penney designated the following people: Richard Brinkman, Catherine Parker, Owen Jones, Catherine Bokar, Judy Strothers, Frank Gaynor, John Caldwell, and Kevin McGhee. Plaintiff objected that the witnesses were not qualified witnesses in that they had not done a sufficient investigation and were not knowledgeable.

C. J.C. Penney's Actions Following Receipt of Notice for Glassware

On December 31, 2001, Plaintiff served J.C. Penney with a 60-Day Notice of alleged violation of Proposition 65 for selling certain painted glassware containing lead without a clear and reasonable warning. See Exhibit 92. The notice specifically referenced only San Nicolo OTR/DOF Romania, Style:98306 SN, and identified Dansk International Designs as the manufacturer of the products at issue. In or around January 2002, after receiving Plaintiffs 60-day notice regarding glassware, Richard Brinkman contacted Steve Carlson at Lenox regarding the San Nicolo products. Mr. Carlson informed Mr. Brinkman that they were reformulating the product. (Brinkman Trial Testimony, 9/16/03.) Mr. Brinkman also confirmed that the San Nicolo products were essentially out of stock, so no stop-sale was issued. The only other hand painted glassware carried by J.C. Penney in January 2002 was manufactured by PGM in Romania. Mr. Brinkman confirmed that the PGM product did not contain lead in the pigment. As a precautionary measure, Mr. Brinkman advised the suppliers of the painted glassware that

he was negotiating new orders with (namely Gibson, Home Essentials and Salton) to both keep paint out of the lip and rim area, as well as, place Proposition 65 warnings on the boxes.

J.C. Penney filed a Demurrer on June 11, 2002, which came on for regular hearing on July 18, 2002. This Court found that the Plaintiff's "60-Day Notice", and the ensuing Complaint, adequately complied with all of the notice requirements of California Health & Safety Code, Section 25248.7, such as to give Defendant adequate description of the products at issue and adequate notice of Plaintiffs claims against them. Based upon these and other findings, J.C. Penney's Demurrer was overruled. On October 21, 2002, Defendants filed their petition for writ of mandate contesting the ruling on Demurrer. On November 7, 2002, the First Appellate District denied Defendants' petition for writ of mandate without comment.

J.C. Penney filed a Motion for Summary Judgment on December 24, 2002 contending that there was no triable issue of fact, since Plaintiff had released J.C. Penney from liability for sale of Markwins products as a result of his settlement with Markwins, was limited to the Markwins products by his 60-day notice, and had failed to identify any other allegedly violative cosmetic kits. After a continuance to allow Plaintiff to conduct discovery, that motion was heard on June 23, 2003, and denied in an order dated September 8, 2003.

On January 15, 2003, Plaintiff served a deposition notice on J.C. Penney that identified Certified International Sunrise and Flora Goblets as painted glassware that contained lead. (Exhibit 193.) On January 27, 2003, Plaintiffs second supplemental interrogatory responses identified Certified International Sunrise Goblet, Certified International Midnight Christmas Set, and Certified International Flora Goblet. (Exhibit 6Rs.) On February 5, 2003, the deposition of Plaintiff Michael DiPirro was taken but no additional painted glassware products were identified as being at issue in the lawsuit. On February 21, 2003, Plaintiff served his third supplemental responses to J.C. Penney's first set of discovery that identified Certified International Midnight Christmas.

(Exhibit 6Ss.) On April 21, 2003, Plaintiff served his fourth supplemental responses to J.C. Penney's first set of discovery and identified Salton At Home Jonal Hudson Valley 5 Piece set; Libbey Orchard Fruit 12 pc glassware set, J.C. Penney Glass Ice Tea, Home Essentials and Beyond (Country Garden set of 4 14 oz. hand painted goblets, Flamingo set of 4 hand painted Wine Glasses, Vintage hand painted collection set of four Fine Hand Painted Wine Goblets, Golden Orchard set of 4 hand painted Goblets, 18 oz.); Gibson Elite (crazy Daisies 5 piece Drinkware Set, Tropical Delight 5 piece Drinkware Set); Pfaltzgraff French Quarter Set/ 4 coolers, 15 oz;. (Exhibit 6Ts).

Plaintiff for the first time produced summary lead testing results with his fourth supplemental interrogatory responses. On May 1, 2003, Plaintiff's supplement to his fourth supplemental interrogatory responses identified Pfaltzgraff Rio & Orleans. (Exhibit 6Ts.)

Plaintiff did not produce documents identifying the laboratory testing of the glassware until after the commencement of trial, claiming that discovery prior to that time was precluded by the work product doctrine.

At the beginning of trial, Plaintiff also served discovery on J.C. Penney in the form of Special Interrogatories and Requests for Production. The July 31, 2003 hearing before the Court narrowed the breadth and scope of this discovery significantly, including developing a definitive definition of "cosmetic kit". Defendant J.C. Penney served responses to Plaintiff's first set of trial discovery on August 8, 2003. The responses identified cosmetic products that were both within and outside of the Court's definition of "cosmetic kit". J.C. Penney also identified additional decorated glassware.

SUMMARY OF APPLICABLE LAW

I. LEGAL BACKGROUND

A. *Proposition 65*

"The Safe Drinking Water and Toxic Enforcement Act of 1986," commonly known as Proposition 65 (Health & Safety Code §§ 25249.5 et seq.), was adopted by the people of California on November 4, 1986. The initiative declared the public's right to protect

themselves against and to be informed about exposures to chemicals that cause cancer, birth defects, or other reproductive harm. See Proposition 65, § 1(a), (b).

Proposition 65 requires the Governor of the State of California to list the chemicals that are "known" to cause cancer or reproductive toxicity in the California Code of Regulations. Health & Safety Code 25249.8. The initiative has two main provisions. First, it bans the discharge of listed chemicals into sources of drinking water. Health & Safety Code § 25249.5. Second, the Act requires that a warning be given for exposures to listed chemicals above certain levels. Health & Safety Code § 25249.6. With regard to that warning requirement, § 25249.6 provides as follows:

> "No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10."

Section 25249.12 provides that the Governor shall designate a "lead agency" to implement the provisions of Proposition 65. The lead agency is empowered to adopt regulations, as necessary, in order to conform with and implement the purposes of the initiative. *Id.* On January 6, 1987, the governor designated as lead agency the state Health and Welfare Agency (Agency). (Executive Order D-61-87 (Jan. 6, 1987); *see Ingredient Communication Council, Inc. v. Lungren*, 2 Cal.App.4th 1480, 1485 (1992)).[14] "Lead" was listed by the governor as a reproductive toxin on February 27, 1987 (22 Cal. Code Regs. § 12000(b)). Lead was included in the initial list of known carcinogens and reproductive toxins based on the requirement that the governor list all chemicals included in Labor Code § 6382. *AFL-CIO v. Deukmeijian*, 212 Cal.App.3d 425, 432 (1989) (reproductive toxins that were included in the initial list on February 27, 1987 "'includes ALL known human reproductive toxicants as listed by the U.S. Department of Labor's Occupational Safety and Health Administration (OSHA)'" (emphasis in original)).

[14] In 1991, when the California Environmental Protection Agency was created, the Governor transferred "lead agency" responsibilities to Cal/EPA's Office of Environmental Health Hazard Assessment ("OEHHA"). (Executive Order W-15-91 (July 17, 1991); *see People ex rel. Lungren v. Superior Court*, 14 Cal.4th 294, 310 & fn. 6 (1996)).

In furtherance of its duty to implement the Act, CHWA adopted emergency regulations during 1987-1988, and by 1989 adopted a series of final regulations that included definitions (See 22 Cal. Code Regs. Division 2, Articles 1-3, and Final Statement of Reasons (Exhibit 1004)), warnings (See Final Statement of Reasons, Article 6 (Exhibit xxxx), and exemptions from the warning requirement (See 22 Cal. Code Regs. Division 2, Articles 7 and 8, and Final Statement of Reasons (Exhibit G)) and methods of detection (See 22 Cal. Code Regs. Division 2, Article 9, and Final Statement of Reasons (Exhibit xxx). The implementing regulations were codified at 22 Cal. Code Regs. § 12000 et seq. In 1996, OEHHA adopted a regulation governing the provision of 60-day notices. 22 Cal. Code Regs. § 12903, and Final Statement of Reasons (Exhibit xxx).

The Proposition 65 regulations define "expose" to mean, "to cause to ingest, inhale, contact via body surfaces or otherwise come into contact with a listed chemical." 22 Cal. Code Regs. § 12102(i). The exposure at issue is only to chemicals listed under Proposition 65. *Consumer Cause, Inc. v. Arkopharma, Inc.*, 106 Cal.App.4th 824, 829 (2003); *Consumer Cause, Inc. v. Weider Nutrition International, Inc.*, 92 Cal.App.4th 363, 369 (2001). "[T]he Health and Welfare Agency has broadly defined the term 'exposure' to include all anticipated means of bringing individuals into contact with chemicals. Examples of these means are provided to further clarify that the Act prohibits all means of directly bringing individuals into contact with chemicals known to the state to cause cancer or reproductive toxicity without clear and reasonable prior warning." *Consumer Cause, Inc. v. Weider Nutrition International, Inc.*, 92 Cal.App.4th at 368, citing FSOR, 22 CCR at 29. The Attorney General reasons: "while the regulation provides examples of types of exposure, e.g., ingestion, inhalation, each type is inextricably tied to the phrase 'come into contact[.]' 'Contact' occurs at the first point at which the body connects with a chemical from outside the body." *Id.* at 369.

The Proposition 65 regulations define " knowingly" as "knowledge of the fact that a discharge of, release of, or exposure to a chemical listed pursuant to Section 25249.8(a) of the Act is occurring. No knowledge that the discharge, release or exposure is